UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(609) 989-2040

CHAMBERS OF
TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE

U.S. COURTHOUSE
402 E. STATE STREET, RM 6052
TRENTON, NJ 08608

November 29, 2010

LETTER ORDER

Re: SPD Swiss Precision Diagnostics GmbH v. Church & Dwight Co., Inc.
Civil Action No. 09-1802 (FLW)

Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics GmbH
Civil Action No. 10-276 (FLW)

Dear Counsel:

As you are aware, pending before the Court is SPD Swiss Precision Diagnostics GmbH's ("SPD") request that the Court require Church & Dwight Co., Inc. ("Church & Dwight") to produce certain documents related to its communications with the U.S. Food and Drug Administration (the "FDA"), which concern Church & Dwight's potential advertising claim that its First Response Early Result pregnancy test is "over 99% accurate." Specifically, SPD seeks the production of all documents, including correspondence between Church & Dwight and the FDA, relating to Church & Dwight's February 2010 510(k) application to the FDA, in which Church & Dwight seeks approval of its proposed "over 99% accurate" statement for its First Response Early Result pregnancy test.[1]

[1]Pursuant to the Medical Device Amendments of 1976, 21 U.S.C. § 360 *et seq.*, anyone seeking to market a Class II device are required to make a Premarket Notification to the FDA. These Premarket Notifications are commonly known as "510(k)" applications. *See* 21 U.S.C. § 360(k).

SPD argues that the documents it seeks are relevant to the above-captioned matters because "SPD is challenging Church & Dwight's 'unsurpassed accuracy' claim on the ground that FR Early Result is not 99% accurate[,]" and, if, as it claims, Church and Dwight is seeking the FDA's approval of a claim that the First Response Early Result pregnancy test is "over 99% accurate," then Church & Dwight's support for that claim as well as the FDA's responses thereto "bear directly on the merits of the dispute." (6/22/10 Ltr. from SPD to the Hon. Tonianne J. Bongiovanni, U.S.M.J. (the "6/22/10 Ltr.") at 2). SPD also argues that the documents must be produced because Church & Dwight submitted excerpts of its February 2010 510(k) application in its motion to dismiss SPD's claim pursuant to the doctrine of primary jurisdiction. Further, SPD notes that Church & Dwight has agreed to produce all other communications with the FDA, including other 510(k) applications, and argues that that material has not only been relevant, but "highly probative." (*Id.*)

Church and Dwight opposes SPD's request for all documents relating to its February 2010 510(k) application and specifically objects to producing correspondence between Church & Dwight and the FDA about the pending application. Church and Dwight argues that such documents, which bear on a "'*contemplated* advertising claim,' not a claim that Church & Dwight is *actually making* or that SPD is *actually challenging* in this case" are not relevant to the pending matters. (7/1/10 Ltr. from Church & Dwight to the Hon. Tonianne J. Bongiovanni, U.S.M.J. at 1 (quoting 6/22/10 Ltr. at 1) (emphasis in original)). While Church & Dwight does not believe that any documents regarding the issue of whether its First Response Early Result pregnancy test is 99% accurate on the day of a woman's expected period, it has agreed to produce the testing documents relevant to that claim. Church and Dwight, however, argues that "[t]he assertion that any other aspect of the pending 510(k) -- including the FDA's interim, non-final reactions to Church & Dwight's scientific proof --

is relevant is senseless because "[w]hat matters are the test protocol and test results themselves, *not* what the FDA has to say about them on a non-final basis." (*Id.* at 4-5 (emphasis in original)). Moreover, Church & Dwight argues that it did not concede that the February 2010 510(k) and all documents relating thereto were relevant when it referenced same in its motion to dismiss. Instead, Church & Dwight claims that in support of its primary jurisdiction defense it "proffered a few pages from its pending 510(k) application for the sole purpose of showing that Church & Dwight is indeed seeking FDA approval for the statement 'Over 99% Accurate from the day before your expected period.'" (*Id.* at 3-4).

At this juncture, the Court shall not require Church & Dwight to produce the pending 510(k) application or correspondence between Church & Dwight and the FDA regarding same to SPD. The Court shall, however, require Church & Dwight to produce all testing documents, including the test data provided to the FDA, that relates to the conclusion that Church & Dwight's First Response Early Result pregnancy test is 99% accurate on the day of EMP (i.e. a woman's expected period). In coming to this conclusion, the Court notes that Church & Dwight's February 2010 510(k) involves an advertising claim that Church & Dwight is not currently making and that SPD is not challenging. While the Court believes that the testing information related to that advertising claim falls within the broad scope of discovery permitted in Federal Court, it also finds that the FDA's non-final reactions to same do not. *See* FED.R.CIV.P. 26(b). Further, the Court finds that Church & Dwight did not

open the door to the wholesale discovery of all documents concerning the February 2010 510(k) application by referring to same in its motion to dismiss in order to attempt to establish its primary jurisdiction defense.

IT IS SO ORDERED.

IT IS FURTHER ORDERED THAT CHURCH & DWIGHT SHALL MAKE THE ABOVE-DESCRIBED PRODUCTION OF DOCUMENTS NO LATER THAN DECEMBER 20, 2010.

TONIANNE J. BONGIOVANNI
United States Magistrate Judge